Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparing the Effect of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Protocol summary

Study aim

Determine the impact of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Design

The clinical trial has a control group based on parallel groups. Assignment of patients to three groups receiving vitamin D and SRP, vitamin D and calcium and SRP and SRP will be done by block method alone and using 6 blocks.

Settings and conduct

Individuals who have referred to the periodontics department of Qom Dental School will enter the study after obtaining informed consent.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people with an average age of 20 to 70 years old. They have more than 20 teeth left in his mouth. At least two interproximal areas with CAL (clinical attachment level) more than 3 mm. Exclusion criteria: people with systemic problems such as diabetes, hypothyroidism or hyperthyroidism and any endocrine-related diseases. Severe systemic diseases such as cancer. Consumption of vitamin D and calcium during the three months before the study. Pregnancy and lactation. People who have received non-surgical periodontal treatment or periodontal surgery in the past year. Use of antibiotics and immunosuppressive drugs that affect the metabolism of vitamin D and calcium.

Intervention groups

Interventions: patients with chronic periodontitis whose vitamin level is less than 32 ng / ml are included in the study. For all patients, Scaling & Root Planning of the whole mouth and then health education is done similarly by flossing and brushing with modified Bass. Then, after two weeks, the first group is given 50,000 IU weekly vitamin D and 1,000 mg of daily calcium supplement, and the second group is given only 50,000 IU weekly vitamin D for 3 months, and the third group as the control group is not given any medication.

Main outcome variables

Periodontal clinical parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051255N1**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-05, 1400/04/14**
Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Fateme Abedini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3660 2455

Email address

dentistryabedini74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effect of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022

Public title
Comparing the Effect of Short-Term Use of Vitamin D with Vitamin D Plus Calcium Supplement in Treatment of Patients with Periodontitis Referred to Qom Dental School from 2021 to 2022
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with an average age of 20 to 70 years old They have more than 20 teeth left in his mouth At least two interproximal areas with CAL (clinical attachment level) more than 3 mm.
Exclusion criteria:
People with systemic problems such as diabetes, hypothyroidism or hyperthyroidism and any endocrine-related diseases Severe systemic diseases such as cancer Consumption of vitamin D and calcium during the three months before the study Pregnancy and lactation People who have received non-surgical periodontal treatment or periodontal surgery in the past year Use of antibiotics and immunosuppressive drugs that affect the metabolism of vitamin D and calcium
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Assigning patients to three groups receiving vitamin D and SRP, vitamin D and calcium, and SRP and SRP alone.It will be done by blocking method and using 6 blocks. Patients are divided into three groups using a randomized balanced block method with a block size of 6. A random sequence is created by an epidemiologist by running an online application on the website (https://www.sealedenvelope.com)
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences
Street address
No. 83, Jihad Daneshgahi Alley, Shahid Lotfi Niasar (Alley No. 4), Safashahr St.
City
Qom
Province
Ghoum
Postal code
37169-93456
Approval date
2021-05-02, 1400/02/12
Ethics committee reference number
IR.MUQ.REC.1400.035

Health conditions studied

1

Description of health condition studied
Periodontitis
ICD-10 code
K05.32
ICD-10 code description
Chronic periodontitis, generalized

2

Description of health condition studied
Vitamin D deficiency
ICD-10 code
E55
ICD-10 code description
Vitamin D deficiency

Primary outcomes

1

Description
Probing depth
Timepoint
Baseline, three months later
Method of measurement
Periodontal probe

2

Description
Clinical attachment loss
Timepoint
Baseline, three months later
Method of measurement
Periodontal probe

3

Description
Bleeding on probing
Timepoint
Baseline, three months later
Method of measurement
Periodontal probe

4

Description
Plaque index
Timepoint
Baseline, three months later
Method of measurement
Determination of plaque score according to O'Leary method

5

Description
Gingival index
Timepoint
Baseline, three months later
Method of measurement
Observation

Secondary outcomes

1

Description
25-hydroxyvitamin D
Timepoint
During the study
Method of measurement
Venous blood sampling

Intervention groups

1

Description
The first Intervention group: Scaling & Root Planning of the whole mouth and then hygiene training is done similarly by flossing and brushing with the modified Bass method. After two weeks of SRP, Prescribe 50,000 IU of vitamin D weekly and 1,000 mg of calcium supplement daily.
Category
Treatment - Drugs

2

Description
The second intervention group: Scaling & Root Planning of the whole mouth and then hygiene training is done similarly by flossing and brushing with the modified Bass method. After two weeks of SRP, Prescribe 50,000 IU of vitamin D weekly.
Category
Treatment - Drugs

3

Description
Control group: Scaling & Root Planning of the whole mouth and then hygiene training is done similarly by flossing and brushing with the modified Bass method. No medication is prescribed for this group as a control group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Qom Dental School-Periodontics depatment
Full name of responsible person
Dr.Leila Khodadadifard
Street address
Qom School of Dentistry, Lavasani St.
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Postal code
3713649373
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. Ehsan Sharifipoor
Street address
No 83, Jihad Daneshgahi Alley, Shahid Lotfi Niasar (Alley No. 4), Safashahr St.
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Phone

+98 25 3285 2720

Email

research@mail.muq.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghoum University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Fateme Abedini

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Qom Dental School, Shahid Lavasani St.

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dentistryabedini74@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr. Leila Khodadadifard

Position

Periodontist, Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Fateme Abedini

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

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Phone

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Email

dentistryabedini74@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after unidentified individuals

When the data will become available and for how long

access the data 6month after the result are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

People working on patients with periodontitis or vitamin D deficiency

From where data/document is obtainable

Applicants can apply via the following e-mail to receive the required documents or data

dentistryabedini74@gmail.com

What processes are involved for a request to access data/document

Email to the project presenter-Request from the Vice Chancellor for Research-If positive, provide information to the applicant

Comments